

### **REMARKS**

In the present application, claims 1, 2 and 61-104 are pending and stand rejected in the final office action mailed August 15, 2006. It is respectfully submitted that, for the reasons that follow and for reasons presented in the previous response, a prima facie case for rejecting the claims has not been established and withdrawal of the rejections is proper. Reconsideration and allowance of claims 1-2 and 61-104 in view of the remarks that follow is respectfully requested.

### **35 U.S.C. § 102 Rejections**

Claims 1, 2, 66-68, 72 and 73 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,458,638 to Kuslich et al. In the "Response to Arguments" section of the Final office action, the Examiner found unpersuasive Applicants' argument "that the length of the anchor is not sufficient to engage a throughhole." It is respectfully submitted what is being argued is that Kuslich et al. discloses an end cap having retaining clips that project from the body of the end cap. The clips snap behind ribs 146 that extend into the interior space of the cage at the end opening of the cage. The ribs 146 extend into and obstruct the same opening in which the body of the cap is positioned. Thus, Kuslich discloses a cap in which the clips are provided with a length to engage a structure located in the opening in which the cap positioned. There is no disclosure that the retaining clips have any length to engage any structure that is not located within the capped end opening. Furthermore, as shown in Fig. 18, the clips extending from the body of the cap are not elongate, but rather are significantly wider than they are long.

In contrast, claim 1 recites "an occlusion body sized and shaped for blocking the opening; and an elongate anchor projecting from said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end having a lip for engaging the thru-hole, said anchor having a length which reaches from said occlusion body to the thru-hole when the cap is inserted into the opening and said lip is engaged to said thru-hole." Claim 1 recites a structure where the anchor is elongate to

engage a through-hole that is not the opening in which the cap is positioned. The Examiner asserts that the rib is the edge of a throughhole. However, rib 146 defines the opening in which the cap is positioned, and is not a throughhole as recited in claim 1. Accordingly, Kuslich fails to disclose claim 1 and withdrawal of this basis of the rejection is respectfully requested. Claims 2, 66-68, 72 and 73 depend from claim 1 and are allowable at least because claim 1 is allowable.

Claims 75-81 and 87-92 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 5,702,451 to Biedermann et al. In the "Response to Arguments" section of the Final Office Action, the Examiner makes several characterizations of the Biedermann et al. disclosure that are not explicitly or fairly disclosed in the specification or drawings. First, the Examiner asserts that it could not be true that edge portion 20 extends away from the interior of the jacket "because the edge is designed to match the contour of the inner jacket surface." The Examiner also asserts that "if interpreting the Applicant's remarks as requiring the prongs to be outside the jacket, the noses (15) that are radially outside the prongs (21, 21') could not lie in the V-shaped recesses (9,10) if the prongs were outside the jacket while engaged therewith." The Examiner then asserts that in Biedermann et al. the "disclosure of 'prongs extending beyond the edge 7 or 8' refers to the prongs extending inside the jacket so far that they extend beyond the edges 7 or 8 of the bottom of the V-shaped recesses (9, 10) almost to the base of the V's."

It is respectfully submitted that Applicant's remarks regarding Biedermann et al. do not appear to have been understood, and the interpretation of Biedermann et al. offered in the Final Office Action is not consistent with Biedermann's disclosure. Biedermann et al. discloses that when the ring 12 is positioned at one edge of the jacket, the prongs 21 extend axially from the jacket in a direction away from the opposite edge of the jacket and thus axially away from the interior of the jacket. This is clear from Biedermann et al. because Biedermann et al. teaches that the prongs are cut to different lengths to form various wedge angles to form a wedge shaped insert. If the prongs were oriented into the interior of the cage, there would be no reasons to cut the prongs 21 to form a wedge angle since the outer edges 7, 8 of the cage would contact the vertebral endplates and not the prongs 21, 21'. Furthermore, if the prongs of a first stop member

were positioned in one end of the cage and through the interior to the other end of the cage, it would not be possible to position a second stop member on the other end of the cage since the first stop member would occupy the interior of the cage, contrary to Biedermann et al. where it is clear that stop members are positioned at each end of the cage. See col 2, lines 30-36 and col. 3, lines 21-26. In addition, the statement in Biedermann et al. that "when inserted the prongs extend beyond the edge 7 or 8, resp., of the jacket 1 almost to their base" (col. 3, lines 6-8) refers to the base of the prongs and not the recesses 9, 10. This is made clear at col. 3, lines 10-13, where it is disclosed that the "base of the prongs" is not parallel to the plate 12 in Figs. 8 and 9. Accordingly, it is respectfully submitted that the Examiner's assertion that "Biedermann must mean that the prongs extent away from the edge (7, 8) of the jacket but within the interior of the jacket" cannot be correct since otherwise the entire portion of the disclosure related to cutting the prongs 21 to form wedge angles would be meaningless, and it would be impossible to position stop members on each end of the jacket with the prongs extending through the opposite end.

Furthermore, the Final Office Action asserts that "since edge (20) is designed to match the contour of the inner jacket surface, it would implicitly engage the inner jacket to the extent required by the claims." The assertion is traversed. Biedermann et al. discloses "an edge portion 20 having an outer contour which corresponds to the inner contour of the jacket 1". Biedermann et al. only discloses that the contours correspond to one another. The edge 20 and the inner contour of the jacket can correspond in shape but be of differing size so that there would be no engagement when ring 12 is positioned in the end of the jacket. For example, Biedermann et al. discloses that ring 12 is identical to the ring shown in Fig. 2 (col. 2, lines 66-67) and ring 12 in Fig. 2 is disclosed as having an outer contour that corresponds to the inner contour of jacket 1. See col. 2, lines 16-18. Fig. 6 is a section view of Fig. 7 along line VI-VI. In Fig. 6, edge 20 is not shown as being aligned with any edge of the ring 12, yet both are disclosed as having a contour that corresponds to the contour of the inner surface of the jacket 1. Accordingly, it is not implicit that edge 20 engages the interior of the jacket simply because it is disclosed as having a contour that corresponds to the contour of the inner surface of the jacket.

Independent claim 75 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including a flat outer wall lying in a plane; and an elongate anchor projecting from said occlusion body in a direction transverse to the plane, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location spaced from the plane. As discussed above, Biedermann et al. reference fails to disclose the elements arranged as recited in claim 75. Namely, Biedermann et al. discloses that the second end of prongs 21, 21' is structured to extend axially away from the cage and configured to engage a vertebral body, not the jacket member 1. Therefore, independent claim 75 distinguishes Biedermann et al and is patentable. Additionally, Applicant submits that each of claims 76-81, which either directly or indirectly depend from claim 75, are patentable for at least the reasons supporting the patentability of claim 75.

Independent claim 87 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including at least one osteogenic aperture extending therethrough; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Again, the Biedermann et al. is directed to a cap where edge portion 20 is structured to engage a vertebral body with prongs 21, 21', and the prongs extend axially away from jacket member 1. Therefore, independent claim 87 is patentable over Biedermann et al. and withdrawal of the rejection is respectfully requested. Furthermore, each of claims 88-92, which depend either directly or indirectly from claim 87, is patentable for at least the reasons supporting the patentability of independent claim 87.

**35 U.S.C. § 103 Rejections**

Claims 75 and 77-81 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuslich et al. The Examiner asserts "that it would have been *prima facie* obvious to make the cap of Kuslich et al. at least partially flat on the outer surface when used on the same end as cap (18") of Kuslich for the same reasons that Kuslich does the same in that embodiment." In order to establish a *prima facie* case of obviousness, a reference must, amongst other requirements, teach or suggest all the claim limitations. Manual of Patent Examining Procedure (MPEP) §2142. As discussed above with respect to claim 1, Kuslich et al. fails to teach or suggest a cap including an elongate anchor including a second end structured and configured to engage the fusion device at a location spaced from the plane as recited in claim 75. Therefore, a *prima facie* case of obviousness has not been established because the reference does not teach or suggest all the claim limitations per the requirements of the MPEP § 2142. As such, Applicant respectfully requests that the obviousness rejection of claim 75 be withdrawn. Furthermore, Applicant submits that each of claims 77-81 is patentable for at least the reasons supporting the patentability of independent claim 75.

Claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. in view of Biedermann et al. or PCT Publication No. WO 91/06261 to Ray et al. In the previous response, Applicant's traversed the *prima facie* case for combining these references. No reply of rebuttal of the traversal of the *prima facie* case has been provided.

Applicant submits that the Examiner's suggestion to modify Kuslich et al. to provide apertures in the cap is contrary to the teachings of Kuslich et al. and also would render it unsuitable for its intended purpose. Namely, leading end cap 18 covering axial opening 40 "prevents disk material from migrating through axial opening 40 into chamber 24 during insertion of the implant 10 as well as during the patient's recovery phase." (See Col. 6, Lines 57-61). Additionally, "like leading end cap 18, trailing end cap 20 prevents disk material from entering chamber 24." (See Col. 7, Lines 21-24). Therefore, Kuslich et al. teaches away from apertures in the end cap, and if apertures were added to leading end cap 18 or trailing end cap

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Response to Final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 6 of 13

20, the device of Kuslich et al. would be unsatisfactory for its intended purpose since disk material could enter chamber 24 through the cap.

Claim 61 depends from claim 1 and is patentable at least for the reasons claim 1 is patentable. Furthermore, claim 61 recites that the occlusion body includes osteogenic apertures, said apertures sized to permit bone ingrowth and protein ingress. As noted, Kuslich et al. teaches away from the modification to include this feature and the proposed modification would render the end cap disclosed therein unsatisfactory for its intended purpose. Therefore, withdrawal of this basis of the rejection is respectfully requested. Additionally, claims 62 and 65, which depend from claim 61, are submitted to be patentable for at least the reasons supporting the patentability of claim 61. Claim 74 depends indirectly from claim 1 and is patentable for the reasons provided for claim 1, and is also patentable since the modification of the Kuslich et al. reference to include apertures in the leading and trailing caps would render the cap disclosed therein device unsatisfactory for its intended purpose.

Claim 76 depends from claim 75 and is patentable at least for the reasons claim 75 is patentable as provided above. In addition, claim 76 recites that the occlusion body defines at least one osteogenic aperture to permit bone growth through said occlusion body. Claim 76 is further submitted to be patentable for the same underlying reasons provided above with respect to claim 61.

Claim 87 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including at least one osteogenic aperture extending therethrough; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Claim 87 is submitted as patentable because Kuslich et al. teaches away from the addition of holes to the leading and trailing caps since Kuslich et al. teaches end caps that are solid to prohibit disk material from entering the interior of the fusion device. Additionally, Kuslich et al., as discussed above, fails to disclose an elongate anchor including a second end, wherein said second

end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Therefore, claim 87 is patentable and withdrawal of the rejection thereof is respectfully requested. Claims 88, 93, and 97 depend from claim 87 and are patentable at least for the reasons supporting the patentability of independent claim 87.

Claims 1, 2, 61-64, and 86 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al in view of Kuslich et al. The Examiner asserts that Biedermann et al. discloses a cap with an occlusion body including an anchor projecting therefrom. Furthermore, in view of the teaching of Kuslich et al., the Examiner contends that it would have been obvious to include a lip or barb on the anchor to hold it to the jacket member. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP §2143.01. The teachings of Biedermann et al. have been clarified as discussed above. Specifically, edge portion 20 is structured to extend axially away from cage member 1 such that prongs 21 and 21' can engage a vertebral body. There would be no desirability to add a lip or other cage engaging structure on the ends of prongs 21, 21' since the ends of prongs 21, 21' are positioned remotely from the cage. One having ordinary skill in the art would recognize that adding this feature thereto would increase structure without improving function, thereby increasing manufacturing costs and resultantly making the added feature undesirable. In fact, one skilled in the art may further recognize that adding a lip to prongs 21, 21' could render these structures unsatisfactory for their intended purpose, because the addition of a lip or barb could impede engagement with a vertebral member. Therefore, there is no motivation or desirability to make the proposed modification to the prongs in Biedermann et al., and Applicant respectfully requests withdraw this basis of the rejection of claims 1, 2, 61-64, and 86.

Claims 69, 82, and 83 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. in view of U.S. Patent Publication No. 2002/0138144 to Michelson. Claim 69 depends from claim 1, and each of claims 82 and 83 depend directly and indirectly, respectively, from independent claim 75. Based on their dependency

therefrom, each is submitted as patentable, since as indicated above, the Kuslich et al. reference fails to disclose all of the claim limitations of independent claims 1 and 75. Accordingly, withdrawal of this basis of the rejection of claim claims 69, 82 and 83 is respectfully requested.

Additional reasons supporting the patentability of claims 69 and 83 exist and were argued in applicant's previous response. The Final Office Action fails to address the traversal of the rejection of these claims. Specifically, it was argued that "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP § 2143.01. The Kuslich et al. reference discloses that body 12 is preferably formed from titanium and/or its alloys because of its noncorrosiveness and fatigue resistance. (See Col. 4, Lines 1-4). The reference further discloses that end caps 18, 20 are preferably formed of high density polyethylene because among other characteristics it has a "slippery touch". (See Col. 7, Lines 14-16). This characteristic is valuable since the end caps may come in touch with epidural tissue which would become irritated if the surface were not "slippery". (See Col. 7, Lines 16-19). If Kuslich et al. used biodegradable caps, then the ends of titanium body 12 would become exposed, coming into contact with epidural tissue and causing irritation thereof, making the device unsatisfactory for its intended purposes. Therefore, Applicant respectfully requests withdrawal of this rejection of claims 69 and 83 for these additional reasons.

Claims 82 and 83 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. 2002/0138144). Each of claims 82 and 83 depends directly and indirectly, respectively, from independent claim 75. Based on their dependency therefrom, each is submitted as patentable, since as indicated above, Biedermann et al. fails to disclose all of the claim limitations of independent claim 75. Additionally, this basis of the rejection of these claims was traversed in the previous response and not rebutted in the Final Office Action. Specifically, it was argued that in regard to claim 83, one having ordinary skill in the art would recognize amongst other reasons, that member 11 is placed into jacket member 1 to provide structural support for the jacket member and to engage a vertebral body. If member 11 were biodegradable



then jacket member 1 would lose the support provided by member 11. In view of the forgoing arguments, Applicant submits that each of claims 82 and 83 is patentable over the combination of Biedermann et al. in view of Michelson (U.S. 2002/0138144).

Claim 94 was rejected under 35 USC §103(a) as being unpatentable over Kuslich et al., Biedermann et al., and Ray as applied to claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 in further view of Michelson (2002/0138144). Claim 94 depends directly from independent claim 87 and is submitted as patentable for at least the reasons submitted herein supporting the patentability of independent claim 87. Additionally supporting the patentability of claim 94, as already submitted herein, is that Kuslich et al. and Biedermann et al. teach away from biodegradable end caps. Applicant therefore submits claim 94 is patentable and respectfully requests withdrawal of this ground of rejection.

Claim 70 was rejected under 35 USC §103(a) as being unpatentable over Kuslich in view of U.S. Patent No. 6,605,089 to Michelson. Claim 70 depends directly from independent claim 1 and is patentable for at least the reasons supporting the patentability of independent claim 1 as discussed above.

Claim 84 was rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. Patent No. 6,605,089). Claim 84 depends from independent claim 75 is patentable at least for the reasons claim 75 is patentable as discussed above.

Claims 71 and 85 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. and Michelson (6,605,089) as applied to claim 84 above in further view of French Patent No. 2,710,519 to Robine. Claim 71 depends from claim 1, and claim 85 depends from claim 84. Claims 71 and 85 are patentable for the same reasons supporting the patentability of claims 1 and 84 and Applicant respectfully requests withdrawal of the rejection thereof.

Claim 96 was rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Robine. Claim 96 depends from claim 87, which is patentable for the reasons provided above. Therefore, withdrawal of this basis of the rejection of claim 96 is respectfully requested.

Claim 95 was rejected under 35 USC §103(a) as being unpatentable over Kuslich et al., Biedermann et al., and Ray as applied to 61, 62, 65, 74, 76, 87, 88, 93, and 97 above, and in further view of Michelson (U.S. Patent No. 6,605,089). Claim 95 directly depends from claim 87 which is patentable for reasons asserted herein. Thus, claim 95 is submitted as patentable at least for the reasons supporting the patentability of independent claim 87 and withdrawal of this basis of the rejection is respectfully requested.

Claims 98-103 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. Patent No. 6,650,089). Independent claim 98 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body being composed of a porous material; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body.

The prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142. As discussed above, the Biedermann et al. reference does not suggest or teach a cap including an elongate anchor with a second end structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Instead, edge 20 and prongs 21, 21' are structured and configured to extend axially away from jacket member 1 (fusion device) to engage a vertebral body. Thus, Applicant contends a *prima facie* case of obviousness in regard to claims 98-103 has not been made and respectfully requests withdrawal of the rejection therefrom.

Claim 104 was rejected under 35 USC §103(a) as being unpatentable over Biedermann and Michelson as applied to claims 98-103 and further in view of Kuslich et al. Claim 104 is submitted as patentable at least for the reasons submitted supporting the patentability of claims 98-103. Furthermore, as discussed above, Applicant contends that one having ordinary skill in the art would recognize that there is no motivation or

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Response to Final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 11 of 13

suggestion to add lips or barbs to edge 20 or prongs 21, 21' as such addition would increase structural complexity without gaining a structural advantage. Withdrawal of this basis of the rejection of claim 104 is respectfully requested.

Claims 71, 85 and 96 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. and Michelson (U.S. Patent No. 6,605,089) as applied to claim 70 above, and further in view of Robine. Each of claims 71, 85, and 96 is submitted as patentable at least for the reasons supporting the patentability of each underlying base claim 1, 75, and 87 as discussed above.

Additionally, the prima facie case for rejecting these claims was traversed in the previous response but not responded to in the Final Office Action. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Manual of Patent Examining Procedure (MPEP) § 2141.02. Moreover, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Manual of Patent Examining Procedure (MPEP) § 2143.01. As submitted above, Kuslich et al. is directed to end caps that are structured to keep disk material from migrating into chamber 24 during insertion of the implant as well as during the recovery phase. (See Col. 6, Lines 58-61; Col. 7, Lines 22-24). Adding a threaded hole to the end caps of Kuslich et al. is contrary to the teachings in Kuslich et al. since disk material could migrate into the chamber through the threaded hole. Therefore, Applicant submits that each of claims 71, 85, and 96 is patentable over the Kuslich and Michelson (U.S. Patent No. 6,605,089) in view of Robine, and withdrawal of this basis of the rejection is respectfully requested.

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Response to Final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 12 of 13

Reconsideration and allowance of the present application including claims 1-2 and 61-104 is hereby respectfully solicited. The Examiner is welcome to contact the undersigned to resolve any outstanding issue with regard to the present application.

Respectfully submitted

By: 

Douglas A. Collier  
Reg. No. 43,556  
Krieg DeVault LLP  
One Indiana Square  
Suite 2800  
Indianapolis, Indiana 46204-2079  
(317) 238-6333

Response to Final Office Action  
Ser. No. 10/624,981  
Atty Docket No. MSDI-168/PC566.02  
Page 13 of 13